

MODEL 2100-SX

CALIBRATION TEST AND CUFF VOLUME CALIBRATION/VERIFICATION



Notice





This information has been provided to assist you in meeting the accreditation standards set forth by the Intersocietal Commission for the Accreditation of Vascular Laboratories.

Parks recommends that you perform the complete field calibration procedure on your Parks Flo-Lab after every 1000 hours of use or once a year.




To perform both the calibration test and the cuff volume verification/calibration test, it will be necessary to purchase the calibration test fixture (Parks part #80-2100) and— for units purchased after May 2007— the 1000 ml chamber (Parks part #986-3003-25) from the factory.

Please call Parks Medical Electronics, Inc. at 1-888-356-9522, M-F, 7:00-3:30 PM Pacific Time. We will need the model number of your instrument to provide the correct calibration equipment.

FIELD CALIBRATION

1. Position the Flo-Lab and cart with the back next to a sturdy table or workbench.
2. TURN THE MAIN POWER SWITCH **OFF** () Located on the lower, right-hand side of the cart). Set the monitor on the bench, with its cables and connections intact, and remove the six screws holding the Flo-Lab top cover. Set the cover aside.
3. In the right front corner of the Flo-Lab you will see a grey colored metal box enclosure. Remove the four screws and take off the box cover. Inside the enclosure there are a set of five plug-in circuit boards, and one other board mounted behind and at right angles to the others.
4. Carefully remove the left most plug-in circuit card and replace it with the Model 80 calibration fixture card. The card to be removed should be marked 8.X near the front. Insert the Model 80 calibration fixture with the component side of the board facing to the left. Connect the cable that was furnished with the Model 80 to the jack in the top of the fixture and to the  **EXTERNAL INPUT** jack on the back of the Flo-Lab.
5. Turn **ON** () the Flo-Lab and computer. The computer will boot into Windows and automatically load the Sonova software. From the opening menu choose NEW STUDY. At the next menu choose LOWER ARTERIAL. Enter a first and last name and press enter. This will put you into a PATIENT & STUDY SCREEN. Press escape. Now Choose TEST SELECT, then choose DOPPLER. On the Model 80 calibration fixture, turn the POWER switch **ON** and the CAL. switch to either **CAL A** or **CAL B** position.
6. On the Flo-Lab front panel, press the **DOPPLER / ON** button. The 8 MHz LED should light up. Also verify that the **OUTPUT FILTER - Hz "28"** LED is illuminated. If needed, press the button below the "28" LED until it illuminates. Next press the **MENU** button (directly to left of front panel display) to advance to "5 - EXTERNAL SIGNAL OFF". Press the **UP** button (directly to right of the front panel display) to turn the signal on.
7. Use the **POSITION** knob on the front panel of the Flo-Lab to move the red cursor position to the 1st division from the bottom of the display. Turn the **SIZE** control clockwise until the signal is maximized. Both channels should display an 8 division signal, plus or minus 10%.
8. Press the **5mm / S** button to run the chart recorder. The signal on the chart should be 32 mm plus or minus 3 mm in amplitude.
9. Press **STOP** to stop the chart recorder. Press the **MENU** button to advance to "5 - EXTERNAL ON". Press the **UP** button to turn the signal off. Press **DOPPLER / ON**. Remove the cable between the Model 80 calibration fixture and the EXTERNAL INPUT jack. Switch the Model 80 calibration fixture power **OFF**.
10. On the left side of the Flo-Lab front panel, use the **POSITION** control to center the trace in the grid on the computer monitor. Turn the Flo-Lab **SIZE** control counter-clockwise to set SIZE A and SIZE B both to 85.
11. Start the chart recorder at **5mm / S**, then set the switches on the Model 80 calibration fixture to "**A**" and "**ON**". After 2 or 3 seconds, set the Model 80 to "**B**". Verify that, with the switch on the Model 80 in position "**A**", 5 green LEDs under TOWARD are on; and that in position "**B**", 5 red LEDs under AWAY are on. Switch back and forth from "**A**" to "**B**" several times, then **STOP** the chart recorder to examine it. Press The  key to "freeze" the trace on the computer monitor.
12. The upper trace on the monitor will look like a square wave, 8 divisions in amplitude, the lower trace will be 4 divisions.

FIELD CALIBRATION

13. The chart recorder trace will be like a square wave, 30 mm \pm 3 mm in amplitude.
14. Press the **[F9]** key to re-start the trace on the computer monitor, and start the chart recorder at **5mm / S**. Set the switch on the Model 80 calibration fixture to **OSC**.
15. After a few seconds, press the button below the **MEAN** LED on the Flo-Lab front panel. The 14 Hz filter LED should illuminate, and the signals should drop in amplitude. Repeat pressing the button below the **MEAN** LED to test the other filter settings, then **STOP** the chart recorder. The signal should be very small at 3.5, and a smooth line in the MEAN setting.
16. Exit all the way out of the Sonova software until you are at your Windows Desktop. Now exit Windows by clicking on the Start button in the lower left-hand portion of your screen. Choose SHUT DOWN. Wait until the computer shuts down, then turn **OFF** () the Flo-Lab main power switch. Remove the Model 80 calibration fixture card and replace the 8.X MHz RF card. Check the polarity and install the card with the components facing the left. Replace the enclosure cover.
17. Connect a mercury column and manometer to the **RED** hose that is connected to the channel "A" VPR input. Turn **ON** () the Flo-Lab, then pump the manometer to 40 mm mercury as read on the mercury column. DO NOT USE THE INTERNAL INFLATOR FOR THIS PROCEDURE as the mercury column may be damaged. USE ONLY A HAND BULB TYPE MANOMETER.
18. Take note of the reading under "**CUFF A**" on the front panel display of the Flo-Lab and also the reading in the upper left corner of the computer monitor. The readings must be within 5mm of the mercury column reading.
19. Pump the system pressure to 200 mm on the mercury column. Again compare the readings on the computer monitor and the front panel of the Flo-Lab to the mercury column. The pressure readings must be within 5mm of the mercury column.
20. Move the connections to the **YELLOW** hose and repeat the tests for "B" as done in steps 17, 18 and 19 above. The "B" numbers are in the upper right corner of the computer monitor.
21. Move the connections to the **BLUE** hose. On the front panel of the Flo-Lab press **VPR, VENOUS**, then **C**, in that order, to add "C" to the display. The numbers for cuff C will be in front of the "A" reading on the Flo-Lab LCD display, and in the upper right corner of the computer monitor in place of "B". Repeat the tests in steps 17, 18 and 19 above.
22. Disconnect the mercury column from the Flo-Lab and then TURN **OFF** () THE MAIN POWER SWITCH on the cart. Replace the Flo-Lab top cover and its six screws. Then replace the computer monitor.
23. The calibration tests are now complete. For cuff volume calibration procedure, proceed to next page.

NOTE: For optimum performance of your Flo-Lab system, **use only the hoses furnished with the system**. The calibration of cuff volume and volume change is based on using the nine-foot hoses and adapters as furnished. Any other length or size of tubing or the addition of an in-line air chamber will cause the reported cuff volume to be increased or decreased by the increase/decrease in volume.

CUFF VOLUME VERIFICATION/CALIBRATION

The Flo-Lab is totally automated and requires no additional action by the technologist above and beyond what is normally required to acquire good pulse volume waveforms. Your Flo-Lab has been calibrated at the factory to accurately determine the cuff volume. However, since the goal of calibrated pulse volume waveforms is to provide accurate and repeatable results, the technologist should initially and occasionally verify that the system is performing properly and should also be aware of several factors which can affect the results. The following information is provided to help you obtain the most accurate and meaningful pulse volume amplitude information.

1. On the Flo-Lab front panel, press the **MENU** button and advance to menu # -B-. If needed, press the **UP** button to turn the **VPR CAL** sequence on. Connect the 1000 ml chamber to the **RED** hose that is connected to the channel "**A**" VPR input.
2. Turn **ON** (**I**) the Flo-Lab and computer. The computer will boot into Windows and automatically load the Sonova software. From the opening menu choose NEW STUDY. At the next menu choose LOWER ARTERIAL. Enter a first and last name and press enter. This will put you into a PATIENT & STUDY SCREEN. Press escape. Now Choose TEST SELECT, then choose VPR.
3. On the Flo-Lab front panel, press "**B**", to turn **B** off, then press "**INFLATE**". The Flo-Lab will inflate, deflate, then re-inflate the 1000 ml chamber. As the second inflation starts, the calculated volume of the chamber will appear under the top graph on the computer monitor. The calculated volume should be within 3% of the value marked on the chamber. If not, press the "**MENU**" button to advance to menu # -B-, which will display the "A CAL FACTOR". If the calculated volume was high, press the "**UP**" button to increase the constant. If the volume was low, press "**DOWN**" to decrease the constant. Press "**DEFLATE**", then "**INFLATE**" to repeat the test. Note that an exact match may not occur, since the calculated volume changes by about 10 ml for each digit that the CAL factor is changed. Record the A CAL factor for future reference.
4. Connect the **YELLOW** hose to the 1000 ml volume chamber, press "**A**", to turn A off, and press "**B**", to turn B on. B CAL factor is verified in the same way that A was, except that menu # -B- will display the B CAL factor, and the B volume numbers will be under the lower graph on the computer monitor.
5. The cuff volume calibration test is now complete. Exit all the way out of the Sonova software until you are at your Windows Desktop. Now exit Windows by clicking on the Start button in the lower left-hand portion of your screen. Choose SHUT DOWN, wait for the computer to shut down, then turn **OFF** (**O**) the Flo-Lab main power switch on the cart.